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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,685	01/13/2004	Tomonori Inoue	163852020700	9629

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EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/755,685	Applicant(s) INOUE ET AL.	
	Examiner Patricia C. Mallari	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-8 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/30/04 & 7/16/04</u> | 6) <input type="checkbox"/> Other: _____ |

Claim Objections

Claims 1, 6, and 8, are objected to because of the following informalities:

On lines 2-3 of claim 1, "radial artery or ulnar artery located at the wrist" should be replaced with "the radial artery or ulnar artery located at a wrist of a user";

On lines 3-4 of claim 1, "feeding fluid inside to inflate" should be replaced with "feeding fluid to the fluid bag to inflate it";

On line 10 of claim 1, "to other position" should be replaced with "to another position";

On line 6 of claim 6, "in other position" should be replaced with "in another position" or "in the other position";

On lines 3-4 of claim 8, "in the position coinciding with the non-selected artery of the fixing member to compose a fixing member main body" should be replaced with "in the portion of the fixing member coinciding the location of the non-selected artery such that the continuous portion of the fixing member comprises a fixing member main body";

On line 5 of claim 8, "of which" should be replaced with "having a";

On line 6 of claim 8, "is narrower than" should be replaced with "narrower than that of". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4 and 5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 4 recites the limitation "a spacer

abutting against the wrist". In this case the wrist, or body part, is non-statutory subject matter and cannot positively be claimed. The applicants should replace "a spacer abutting against the wrist" with "a spacer adapted to abut against the wrist" in order to overcome this rejection. Claim 5 recites the limitation "the spacer has a shape of which inner surface is curved along the bone of the wrist", wherein the body part is again non-statutory subject matter, which cannot be claimed positively. The applicants should replace the limitation with "the shape of the inner surface of the spacer is adapted to curve along the bone of the wrist" to overcome this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the fixing member has a shape so as to form a gap at least in part of the wrist surface at which the non-selected artery is located". It is unclear whether the "wrist surface" refers to the surface of the wrist of the user or the surface of the wrist or the surface of the fixing member adapted to contact the wrist, or whether the limitation should actually read "the fixing member has a shape so as to form a gap between the surface of the wrist at the location of the non-selected artery and the surface of an inner surface of the fixing member", as shown in figure 4 of the application. If the surface of the wrist is intended by the limitation, the applicants should

note that the specification lacks sufficient antecedent basis for the fixing member having such a shape that a gap is formed in at least part of the surface of the wrist, and further, it is unclear how the shape of the fixing member would form a gap in such a part of the wrist. If the "wrist surface" refers to the surface of the fixing member contacting the surface of the wrist, the applicants should alter the language to define the relationship more clearly, such as "the wrist surface of the fixing member", but should note that the specification then lacks sufficient antecedent basis for claims 3-5, wherein the cuff further comprises a swollen part or a spacer where the spacer forms the gap. If the limitation is intended to reflect the embodiment shown in figure 4 of the application, the applicants should amend the claim to reflect clearly that intention. For the purposes of this examination only, the examiner will assume that the "wrist surface" refers to the surface of the fixing member that contacts the surface of the user's wrist.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,231,517 to Forstner. Forstner (see entire document) discloses a wrist type blood

pressure meter cuff comprising a fluid bag 23b for oppressing a radial artery 2 (fig. 2) located at the wrist by feeding fluid inside the bag 23b to inflate it and a fixing member, wherein the cuff 22 itself serves as the fixing member for fixing the fluid bag at the wrist (fig. 2; col. 4, lines 29-43 of Forstner). The fixing member 22 has a structure such that the oppressing pressure applied from the fixing member 22 to the wrist at an area at which the non-selected artery is located may be smaller than the oppressing pressure directly applied from the fixing member 22 to another portion of the wrist when oppressing the wrist by inflating the fluid bag 23b, wherein, when the fluid bag 23b is inflated, clearly the pressure applied at the point at which the bag 23b is located is greater than that applied at other points of the fixing member 22.

Claims 1, 2, 6, and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2004/0010198 to Yamakoshi et al.

The applied reference has a common applicant and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Also, the applicants cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Yamakoshi (see entire document) discloses a wrist type blood pressure meter cuff comprising a fluid bag 16 for oppressing the radial or ulnar artery at the wrist of a patient by feeding fluid inside the bag 16 to inflate it, and a fixing member 10a (paragraphs 10013, 0029). The fixing member 10a has a structure such that the oppressing pressure directly applied by the fixing member 10a may be less at the location of the non-selected artery than that of another position when the fluid bag 16 is inflated. For example, the cuff is capable of being placed on the wrist such that a gap 11h or 17 may be placed over the non-selected artery, which would cause the pressure applied when the cuff is in use to be less over the non-selected artery than other areas of the fixing member 11 (figs. 1, 4; paragraphs 0029, 0032, 0039). Also, the bag 16 may be provided only over the selected artery such that the pressure provided by the fixing member 11 at the non-selected artery is less than that at the selected artery (figs. 8, 9A, 9B; paragraphs 0063-0065).

Regarding claim 2, the fixing member 11 has a shape so as to form a gap 11h at a part of the fixing member that contacts the wrist (the wrist surface of the fixing member 11) such that, during use, the gap 11h may be located at the position of the non-selected artery (fig. 4).

Regarding claims 6 and 7, the structure of the fixing member 11 is such that the area with which the fixing member is adapted to directly contact the wrist above the non-selected artery is smaller than the area with which the fixing member is adapted to directly contact another position of the wrist (fig. 4). With further regard to claim 7, the fixing member 11 has an opening 11h or 17, which may coincide with the location of the

wrist above the non-selected artery when the cuff is placed on a user's wrist (figs. 1 & 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being obvious over Yamakoshi, as applied to claims 1, 2, 6, and 7 above.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the

reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Yamakoshi teaches the fixing member 11 of the cuff including a discontinuous portion 11h or 17, which may coincide with the location of the non-selected artery when the cuff is placed on a user's wrist, such that the continuous portion of the fixing member 11 can be considered the fixing member main body. The coupling member, formed either by the narrow portion of the fixing member 11 surrounding the gap 11h (fig. 4) or by the rail 14 (figs. 1 & 2), lacks a width in the longitudinal direction of the artery that is narrower than that of the fixing member main body. However, the applicants have not disclosed that such a width of the coupling member solves any stated problem or is for any particular purpose. Moreover, it appears that the cuff would perform equally well with the coupling member having any width. Accordingly, the width of the coupling member in a longitudinal direction of the artery being narrower than that of the fixing member main body is deemed a design consideration that fails to distinguish patentably over the prior art of Yamakoshi.

Allowable Subject Matter

Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 4 and 5 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 3, the prior art of record fails to teach or fairly suggest a wrist type blood pressure meter cuff comprising a fluid bag and a fixing member that includes a swollen part of at least part of the inner surface of the position of the fixing member coinciding with the non-selected artery, wherein the swollen part is swollen in the outward direction, as claimed.

Regarding claims 4 and 5, the prior art of record fails to teach or fairly suggest a wrist type blood pressure meter cuff comprising a fluid bag and a fixing member, the fixing member having a shape so as to form a gap at least in part of the wrist surface at which a non-selected artery is located, and comprising a spacer adapted to abut against the wrist, wherein the spacer forms the gap in the wrist surface, as claimed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,694,821 to Yamakoshi

US Patent No. 6,514,212 to Ide et al

US Patent No. 6,336,901 to Itonaga et al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Patricia Mallari
Patent Examiner
Art Unit 3736

~~PRIMARY EXAMINER~~
ROBERT L. NASSER

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